

PATENT COOPERATION TREATY PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY PCT

(Chapter II of the Patent Cooperation Treaty)
(PCT Article 36 and Rule 70)

REC'D 08 MAR 2005

Applicant's or agent's file reference 7936/CHB/sxy	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. CT/NZ2004/000057	International filing date (day/month/year) 23 March 2004	Priority date (day/month/year) 8 April 2003	
International Patent Classification (IPC) or national classification and IPC t. Cl. ⁷ B01L 3/00, B01D 39/04, B01L 7/00, B81B 1/00, C12Q 1/68, G01N 35/00			
Applicant AUCKLAND UNISERVICES LIMITED et al			

This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

This REPORT consists of a total of 6 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, comprising:

a. ☐ (sent to the applicant and to the International Bureau) a total of sheets, as follows:

- ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
- ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

c. This report contains indications relating to the following items:

- ☒ Box No. I Basis of the report
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

Date of submission of the demand 4 August 2004	Date of completion of the report 25 February 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer GARETH COOK Telephone No. (02) 6283 2541

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Box No. I Basis of the report

With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1 (b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☐ the description:

pages as originally filed/furnished

pages* received by this Authority on with the letter of

pages* received by this Authority on with the letter of

☐ the claims:

pages as originally filed/furnished

pages* as amended (together with any statement) under Article 19

pages* received by this Authority on with the letter of

pages* received by this Authority on with the letter of

☐ the drawings:

pages as originally filed/furnished

pages* received by this Authority on with the letter of

pages* received by this Authority on with the letter of

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/figs

☐ the sequence listing (*specify*):

☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/figs

☐ the sequence listing (*specify*):

☐ any table(s) related to the sequence listing (*specify*):

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees the applicant has:

☐ restricted the claims.

☐ paid additional fees.

☐ paid additional fees under protest.

☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:

☐ complied with.

☒ not complied with for the following reasons:

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1 to 39 are directed to a DNA analysis system which includes a single unit that affects both extraction of DNA and amplification by identical replication of a region of interest of extracted DNA. It is considered that the single unit of the DNA analysis system that affects both DNA extraction and amplification comprises a first "special technical feature".
2. Claims 40 to 45 are directed to a purification stage for a DNA analysis system comprising a gel filtration unit contained in a conduit, the gel filtration medium being a resin of microscopic, synthetic beads. It is considered that the DNA gel filtration medium comprising a resin of microscopic, synthetic beads comprises a second special technical feature.
3. Claims 53 to 57 are directed to a DNA analysis system including a microfluidic device with a plurality of wells interconnected by channels whereby movement of a sample from one well sequentially to other wells is controlled. It is considered that the microfluidic device with a plurality of interconnected wells comprises a third special technical feature.

Since the abovementioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept, a priori.

4. Consequently, this report has been established in respect of the following parts of the international application:

☒ all parts.

☐ the parts relating to claims Nos.

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Statement

Novelty (N)	Claims 1-39, 48, 49, 54-56	YES
	Claims 40-47, 50-53, 57	NO
Inventive step (IS)	Claims 1-39, 48, 49, 54-56	YES
	Claims 40-47, 50-53, 57	NO
Industrial applicability (IA)	Claims 1-57	YES
	Claims	NO

Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

- D1 US 5 955 029 A (Wilding et al)
- D3 WO 2000/012675 A1 (Molecular Innovations)
- D4 WO 2000/060362 A1 (Young et al)
- D5 Derwent Abstract Accession 2003-816512; JP 2002369682 A (Hitachi Keisokki)
- D6 US 2002/047003 A1 (Bedingham et al)
- D7 Amersham Biosciences, "Sephadex: rapid group separation of high and low molecular weight substances, such as desalting, buffer exchange and sample clean up", Gel Filtration: Principles and Methods, pages 57-70, Amersham Biosciences AB, 2002
- D8 WO 2004/039500

Novelty (N) and Inventive Step (IS) claims 1 to 39

Claims 1 to 39 are directed to a device and method whereby DNA is extracted and amplified in a single device. The extraction method is through use of a proteinase which stable and active in the temperature range of 65°C to 80°C but denatured at a temperature in excess of 90°C. The prior art documents D1 and D3 disclose devices which both extract the DNA and amplify the DNA. However the method of extraction of the DNA differs between the claimed methods and the citation, nor would it be obvious to use a proteinase as defined in the specification with the devices of the citations. Claims 1 to 39 are therefore both novel and inventive.

Novelty (N) and Inventive Step (IS) claims 40 to 45

Claims 40 to 45 are to a gel filtration unit and method of purifying DNA whereby the gel filtration medium is a polysaccharide resin of microscopic beads. In the specification at page 9 lines 7 to 10, the preferred medium is Sephadex G50/G25, produced by Amersham Biosciences AB. The citation D7 discloses Sephadex, G50/G25, its use as a size exclusion gel filtration medium, including for polynucleotides, and filtration unit comprising Sephadex G50/G25. Claims 40 to 45 are therefore not novel.

Novelty (N) and Inventive Step (IS)

Claims 46 to 57 are to a microfluidic device which is used for DNA sample preparation, including extraction and amplification. D1 discloses a microfluidic device which will extract and amplify the DNA from a sample then further analyse the amplification products, such as in figure 12. Claims 46, 47, 50 to 53 and 57 are not novel when compared with this document.

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Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
E, X WO 2004/039500 A1	13 May 2004 (13/05/2004)	30 October 2003 (30/10/2003)	31 October 2002 (31/10/2002)

The citation discloses a DNA analysis system which is operable in the extraction stage and amplification stage and is a microfluidic device with wells interconnected by channels, allowing a sample to moved from one well to another to undergo various stages of preparation. Claims 46 to 53 and 55 to 57 are not novel when compared with this document.

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 46 to 52 are not fully supported by the specification. Claim 46 is defining a DNA analysis system including:
a unit operable for extraction of DNA and amplification of a region of interest of the DNA; and
a microfluidic device, through which a sample undergoes various stages of preparation.

In the description, the microfluidic device is used for sample preparation and for extraction and amplification, and is not separate to the extraction and amplification unit (see figure 5, page 11 lines 22 to 26). Claim 46 is therefore not fully supported by the specification